DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

94704d

January 29, 2004

WARNING LETTER
CHI-3-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kazuo Saito
Chairman and Chief Executive Officer
Omron Healthcare, Inc.
300 Lakeview Parkway
Vernon Hills, IL 60061

Dear Mr. Saito:

During the inspection of your firm on June 24-26, and 30, and July 7 and 10, 2003, our investigators determined that your firm distributes nebulizers, blood pressure monitors, thermometers, and stethoscopes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to review, evaluate, and investigate complaints involving failure of a device to meet its specifications. For example, your firm received complaints L96184, L96452, and L98550 for "Unit Malfunction" of the CompAir Elite Compressor Nebulizer System NE-C21 from lot 025. Letters from complainants state that the units were used for three months or less. The repair reports identify defective printed circuit boards that need replacement but do not list a reason for the replacement. Your firm did not investigate the cause of the printed circuit board failures. [21 CFR 820.198(c)]

2. Failure to establish and maintain procedures for acceptance of incoming product. For example, your firm did not have written procedures for testing the Battery and DC Auto Adapter Model C21BATKIT upon receipt. The Quality Control Supervisor stated that the unwritten procedure was [redacted] which is the Battery Operation Time listed in the C21BATKIT manual. Inspection Request/Disposition Forms P27564, P28289, and P28368 contain samples that did not meet the [redacted] run time but the samples were not documented as rejected and the lots were approved. [21 CFR 820.80(b)]

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints that ensure that all complaints are processed in a uniform and timely manner. For example, your firm's Complaint and Investigation Handling Procedure, QCOP-045, failed to specify the following:

- frequency of complaint threshold reviews,
- groups required to attend,
- how topics discussed and decisions made will be documented.

For the past two years, the only documented Complaint Threshold Meeting occurred on 2/27/03. [21 CFR 820.198(a)(1)]

4. Failure to establish and maintain procedures for implementing and corrective and preventive action. For example, Complaint Investigation Report #32, indicates that your firm implemented [redacted] to the CompAir Elite Compressor Nebulizer System NE-C21 in late 2001 to correct the following problems:

    - Low compression due to loosening of the motor shaft screw.
    - Unit malfunction caused by pressure and heat build up within the Pump Cap pressure plate.

    Your firm failed to document a reason for not taking further action on product distributed before implementation of the manufacturing corrections, as required by your QCOP-017 Recall Procedure. Since 1/1/03, your firm has received [redacted] complaints of low compression and has replaced [redacted] pressure plates. [21 CFR 820.100(a)]

We have additional concerns regarding your firm's complaint handling procedures. For example, your Complaint and Investigation Handling Procedure, QCOP-045, defines the threshold for consideration of investigation as [redacted] by model. Therefore, this procedure does not require your firm to investigate complaints involving failure of a device, labeling, or packaging to meet its specifications, if the complaint rate for a specific model was below [redacted] This procedure does not comply with 21 CFR 820.198(c), which requires an investigation of all complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA-483 issued to you at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. No premarket submissions for Class III devices, to which the Quality System/Good Manufacturing Practice deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge receipt of your firm's response, dated August 27, 2003, to the Form FDA-483. Although it appears from your response that you are working toward correcting the deviations noted at your firm, you must adequately implement and maintain each corrective action to ensure its effectiveness. We will verify the adequacy of your corrective actions during our next inspection. In order to facilitate FDA in making the determination that such corrective actions have been made, you may submit to this office certification by an outside expert consultant that he/she has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the Quality System Regulation (21 CFR Part 820) and verified that you have adequately implemented the corrective actions promised in your response to the Form FDA-483. Along with the certification, we request that you also submit a copy of the consultant's report, and certification by you, as the firm's Chief Executive Officer, that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

Please notify this office, in writing, within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,

/S/

Richard Harrison
Acting District Director